Cover Letter

Cover letter regarding PMN TS SK22BZ 11 July 2013

Good afternoon:

I am submitting a PMN that I thought was originally submitted on 29 March 2013. On that date, I submitted the PMN and received an e-mail confirming receipt; a copy of the text of that e-mail is pasted below:

"The Original document for CDX Transaction ID _2bc712ba-5844-497f-9c37-5846375ae519
was submitted to eTSCA on 03/29/2013 at 10:08:51 EDT

Document Id: _a1199fe5-cdc1-4503-bb45-9ca908ef1489
Document Name: AlPhos_finalized.pmn_tsca"

I understood this to mean that my PMN and attachments had been submitted and was proceeding through the review process. In mid-June, I checked with our technical consultant, who asked me for the PMN number that I should have received. I searched, but realized that notification of the PMN number was never received, so we began investigating the issue. We now understand that our document failed in some way during the submission process and, although we have already waited more than 90-days, our new chemical has yet to be reviewed. Note that we never received any notification that the document failed to be delivered to EPA at any step of the process and since EPA does not allow third parties (who are experts on new chemical submissions) to be the primary point of contact, I had no way of knowing that I should have received more information. After discussing the issue with EPA, we understand that we should have been contacted by one of EPA's contractors who are meant to monitor the process and notify submitters of such issues.

Due to these problems, which seem to be completely beyond our control, we respectfully request an expedited review of the subject PMN. Please call either Beth Bosley or David Diefenthal with any questions.

Best regards,
David Diefenthal Beth Bosley
615.519.3732 724.612.5766

Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038

U.S. ENVIRONMENTAL PROTECTION AGENCY			AGENCY USE ONLY
EPA	**PREMANUFACTURE NOTICE** **FOR NEW CHEMICAL SUBSTANCES**		Date of receipt:
When completed, send this form to:	**If sending by Courier:** Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1201 Constitution Ave NW WASHINGTON, D.C. 20460 Contact Numbers: 202-564-8930/8940	**If sending by US Mail:** Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1200 Pennsylvania Ave NW WASHINGTON, D.C. 20460	**Submission Report Number** ALPH130711979972581

Total Number of Pages	User Fee Payment ID Number	TS Number
39	000723	SK22BZ

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance. For mailing address information see the Help instructions in the e-PMN tool.

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III – LIST OF ATTACHMENTS

For paper submissions, attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

☐	Environmental fate data	☐	Other Data
☐	Health effects data	☐	Risk Assessments
☐	Environmental effects data	☐	Structure/activity relationships
☒	Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.)		
☐	Test data not in the possession or control of the submitter		

TYPE OF NOTICE (Check Only One)

☒	**PMN** (Premanufacture Notice)
☐	**SNUN** (Significant New Use Notice)
☐	**TMEA** (Test Marketing Exemption Application)
☐	**LVE** (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
☐	**LOREX** (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
☐	**LVE** Modification
☐	**LOREX** Modification
☐	**Mock Submission**
☐	Mark (X) if pending Letter of Support

IS THIS A CONSOLIDATED PMN (Y/N)? ____

____ # of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).

☒ Mark (X) if any information in this notice is claimed as confidential.

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CERTIFICATION -- A printed copy of this signature page, with original signature, must be submitted with CD or paper submission.

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture, import or process for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.
2. All information provided in this notice is complete and truthful as of the date of submission.
3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, Consolidated PMN, or SNUN, check the following **user fee** certification statement that applies:

☐	The Company named in Part I, Section A has remitted the fee of $2500 specified in 40 CFR 700.45(b), or
☐	The Company named in Part I, Section A has remitted the fee of $1000 for an Intermediate PMN (defined @ 40 CFR 700.43) in accordance with 40 CFR 700.45(b), or
☒	The Company named in Part I Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45(b).

If you are submitting a **Low Volume Exemption (LVE)** application in accordance with 40 CFR 723.50(c)(1) or a **Low Release and Low Exposure Exemption (LoRex)** application in accordance with 40 CFR 723.50(c)(2), check the following certification statements:

☐	The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.
☐	The manufacturer is familiar with the terms of this section and will comply with those terms; and
☐	The new chemical substance for which the notice is submitted meets all applicable exemption conditions.
☐	If this application is for an LVE in accordance with 40 CFR 723.50(c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 USC 1001.				Confidential
Signature and title of Authorized Official (Original Signature Required)		Date		☒

Part I -- GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential

1a.	Person Submitting Notice (in U.S.)					Confidential
Name of Authorized Official	(first) David		(last) Diefenthal			
Position	President					
Company	JJI Technologies, LLC					☐
Mailing Address (number & street)	1350 Bacon Road					
City	Painesville	State	OH	Postal Code	44077	
email	dief@bellsouth.net					

b.	Agent (if Applicable)					Confidential
Name of Authorized Official	(first)		(last)			
Position						
Company						☐
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)				

c.	Joint Submitter (if applicable)					Confidential
If you are submitting this notice as part of a joint submission, mark (X)					☐	
Name of Authorized Official	(first)		(last)			
Position						
Company						☐
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)				

2.	Technical Contact (in U.S.)					Confidential
Name of Authorized Official	(first) Beth		(last) Bosley			
Position	President					
Company	Boron Specialties					☐
Mailing Address (number & street)	1350 Bacon Road					
City	Painesville	State	OH	Postal Code	44077	
e-mail	44077	Telephone (include area code)			724-612-5766	

			Mark (X) if none	Confidential
3.	If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number.		☒	☐
4.	If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete).		☒	☐
5.	If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.	XXX	☐	☒

6.	Type of Notice – Mark (X)						
1.	Manufacture Only ☒	Binding Option ☐	2.	Import Only ☐	Binding Option ☐	3.	Both ☐

Part I – GENERAL INFORMATION -- Continued

Section B – CHEMICAL IDENTITY INFORMATION: You must provide a currently correct Chemical Abstracts (CA) name of the substance based on current CA index nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either Item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. ☐

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)	Class 1	Class 2	CBI
a. Class of substance - Mark (X)	X	☐	☐

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, which ever is appropriate based on current CA index nomenclature rules and conventions). X

XXX

CAS Registry Number (if a number already exists for the substance): XXX

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice)	X	IES Order Number	321142	**Method 2** (Other Source)	☐

Enter Attachment filename for Part I, Section B, 1. c.: IES_Report_DP-111 SANITIZED.jpg ☐

d. Molecular formula: XXX X

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance, provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained. ☐

See Attachment 001 (Structure for PMN_SANITIZED.pdf)

Enter Attachment filename for Part I, Section B, 1. e.: Structure for PMN_SANITIZED.pdf ☐

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For a class 2 substance - (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate).	Confidential

e. (1) List the immediate precursor substance names with their respective CAS Registry Numbers. ☐

Enter Attachment filename for Part I, Section B, 1. e. (1)		☐

e. (2) Describe the nature of the reaction or process. ☐

Enter Attachment filename for Part I, Section B, 1. e. (2)		☐

e. (3) Indicate the range of composition and the typical composition (where appropriate). ☐

Enter Attachment filename for Part I, Section B, 1. e. (3)		☐

Part I -- GENERAL INFORMATION – Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. Polymers (For a definition of polymer, see the Instructions Manual.)	Confidential
a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.	☐

Describe the methods of measurement or the basis for your estimates:

GPC ☐	**Other** (Specify Below) ☐	

Specify Other:

(i) lowest number average molecular weight:	(ii) maximum weight % below 500 molecular weight:	(iii) maximum weight % below 1000 molecular weight:

Enter Attachment filename for Part I, Section B, 2. a. ☐

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential

(1) - Provide the specific chemical name and CAS Registry Number (if a number exists) of each monomer or other reactant used in the manufacture of the polymer.
(2) - Mark (X) this column if entry in column (1) is confidential.
(3) - Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) - Choose "yes" from drop down menu if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) - Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) - Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) - Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant specific chemical name (**1**)	CBI (**2**)	Typical composition (**3**)	Include in identity (**4**)	CBI (**5**)	Max residual (**6**)	CBI (**7**)
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						

Mark (X) this box if the data continues on the next page. ☐

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c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice (check one).				CBI
Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice) ☐	IES Order Number		**Method 2** (other source) ☐	
Enter Attachment filename for Part I, Section B, 2. c.				☐

d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.	☐

CAS Registry Number (if a number already exists for the substance)		

e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.	☐

Enter Attachment filename for Part I, Section B, 2. e.		☐

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. Impurities
   (a) - Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purpose. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
   (b) - Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity (a)	CAS Registry Number (a)	Maximum Percent % (b)	Confi-dential
Water	7732-18-5	0.1	
XXX	XXX	XXX	X

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part I, Section B, 3. ☐

4. Synonyms - Enter any chemical synonyms for the new chemical identified in subsection 1 or 2.
XXX ☒

Enter Attachment filename for Part I, Section B, 4. ☐

5. Trade identification - List trade names for the new chemical substance identified in subsection 1 or 2.
DP-111 ☐

Enter Attachment filename for Part I, Section B, 5. ☐

6. Generic chemical name - If you claim chemical identify as confidential, you must provide a generic name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

Aluminum phosphate

Enter Attachment filename for Part I, Section B, 6.

7. Byproducts - Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confi-dential
XXX	XXX	X

Mark (X) this box if the data continues on the next page. ☐

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

The information on this page refers to consolidated chemical number(s): ☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6**

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume -- Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume.

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (X)
XXX	XXX	☒	☐

Enter Attachment filename for Part I, Section C, 1. | | CBI ☐

2. Use Information -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) --Describe each intended category of use of the new chemical substance by function and application.
(2) --Mark (X) this column if entry column (1) is confidential business information (CBI).
(3) --Indicate your willingness to have the information provided in column (1) binding.
(4) --Estimate the percent of total production for the first three years devoted to each category of use.
(5) --Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) --Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) --Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) --Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.
(9) --Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (**1**) (by function and application i.e. a dispersive dye for finishing polyester fibers)	CBI (**2**)	Binding Option Mark (X) (**3**)	Production % (**4**)	CBI (**5**)	% in Formulation (**6**)	CBI (**7**)	% of substance expected per use (**8**)					CBI (**9**)
							Site-limited	Consumer*	Industrial	Commercial	Binding Option	
Flame retardant for industrial plastics			100		XXX	X	10	0	90	0		

* If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

Mark (X) this box if the data continues on the next page. ☐

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instruction Manual for examples of generic use descriptions.

Enter Attachment filename for Part I, Section C, 2. b. | | CBI ☐

3. Hazard Information -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the new substance. List in part III hazard information you include.

		Binding Option Mark (X)
Mark (X) this box if you attach hazard information.	☒	☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the "Confidential" box next to any item you claim as confidential

The information on pages 8 and 8a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control. Importers do not have to complete this section for operations outside the U.S.; however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual

1. Operation description
   a. Identity -- Enter the identity of the site at which the operation will occur.

				Confi-dential
Name	JJI Technologies			
Site address (number and street)	1350 Bacon Road			☐
City	Painesville	County	Lake County	
State	OH	ZIP code	44077	

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet, and if any of the sites have significantly different production rates or operations, include all the information requested in this section for those sites as attachments. → 1 ☐

Mark (X) this box if the data continues on the next page. ☐

b. Type -- Mark (X) Manufacturing [X] Processing ☐ Use ☐ ☐

c. Amount and Duration -- Complete 1 or 2 as appropriate

				Confi-dential
1. Batch	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year	[X]
	XXX	XXX	XXX	
2. Continuous	Maximum kg/day (100% new chemical substance)	Hours/day	Days/year	☐

d. Process description — Mark (X) to indicate your willingness to have your process description binding. → ☐

(1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.).
(2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

[X]

XXX

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Diagram of the major unit operation steps.	Confidential ☐

See Attachment 002 (PFD_PMN_DP-111_SANITIZED.pdf)

Enter Attachment filename for Part II, Section A, 1. d.	PFD_PMN_DP-111_SANITIZED.pdf ☐

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Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

The information on pages 9 and 9a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

2. Occupational Exposure -- You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) -- Describe the activities (i.e. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
(2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) -- Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) -- Indicate your willingness to have the information provided in column (3) or (5) binding.
(5) -- Indicate the physical form(s) of the new chemical substance (e.g., solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
(7) -- Mark (X) this column if entries in columns (3) and (5) are confidential business information (CBI).
(8) -- Estimate the maximum number of workers involved in each activity for all sites combined.
(9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (i.e., bag dumping, filling drums) (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (X) (4)	Physical form(s) & % new substance (5)	Binding Option Mark (X) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum Duration		CBI (12)
									Hrs/Day (10)	Days/Yr (11)	
A - packaging product from dryer		Local exhaust ventilation Respirator Tyvek suit Nitrile gloves		Solid, 100%			1		1	190	

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part II, Section A on the bottom of page 9a. ☐

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3. Environmental Release and Disposal -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the new substance will be released from that release point.
(5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number	Amount of New Substance Released		CBI	Medium of release e.g. Stack air	Control technology and efficiency (you may wish to optionally attach efficiency data)			CBI
(1)	(2a)	(2b)	(3)	(4)	(5a)	Binding Mark (X)	(5b)	(6)
1	0.2 kg/batch	0.8 kg/batch		Fugitive Air	Dust collector		0.1 kg/batch	

Mark (X) this box if the data continues on the next page. ☐

(7) Mark (X) the destination(s) of releases to water.		NPDES#	CBI
☐ POTW--provide name(s)			☐
☐ Navigable waterway- - provide name(s)			☐
☒ Other--Specify	No water releases expected		☐

Enter Attachment filename for Part II, Section A. ☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

The information on pages 10 and 10a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the new chemical substance*. If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1(a). Operation Description -- To claim information in this section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

(1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify - e.g. 5 gallon pails, 55 gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity.

(2) -- Either in the diagram or in the text field 1(b) below, provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch).

(3) -- Either in the diagram or in the text field 1(b) below, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

(4) -- Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

	Number of Sites	XXX	Confidential	X

See Attachment 003 (USE_PFD_PMN_DP-111_SANITIZED.pdf)

1(b). (Optional) This space is for a text description to clarify the diagram above. Confidential X

XXX

Enter Attachment filename for Part II, Section B on the bottom of page 10a.	USE_PFD_PMN_DP-111_SANITIZED.pdf	☐

Continuation Sheet

ID	P10SB1(a)(4)1	Field	Part II, Section B, 1(a)(4). Operation Site Locations

XXX

PMN Page 10a

2. Worker Exposure/Environmental Release

(1) -- From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) -- Estimate the number of workers exposed for all sites combined.
(4) -- Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) -- Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.
(7) -- Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) -- From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) -- Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) -- Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) -- Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity	# of Workers Exposed	CBI	Duration of Exposure		CBI	Protective Equip./Engineering Controls/Physical Form	% new substance	% in Formulation	CBI
(1)	(2)	(3)	(4a)	(4b)	(5)	(6)	(6)	(7)	(8)
A	10		1	200		XXX	XXX	XXX	X

Release Number	Amount of New Substance Released		CBI	Media of Release & Control Technology	CBI
(9)	(10a)	(10b)	(11)	(12)	(13)
1	0.2 kg/batch	0.8 kg/batch		0.2 kg/batch estimated released as a fugitive air emission 0.8 kg/batch estimated released into air handling equipment, with product captured and (likely) disposed via offsite incineration.	

Mark (X) this box if the data continues on the next page. ☐

(14) Byproducts:	None known	(15) CBI ☐

Enter Attachment filename for Part II, Section B. ☐

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in the following section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, and/or raw materials substitution. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Quantitative or qualitative descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction in addition to compliance with existing regulatory requirements. The EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other media (e.g., air to water) or nonenvironmental areas (e.g., occupational or consumer exposure). To the extent known, information about the technology being replaced will assist EPA in its relative risk determination. In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

Describe the expected net benefits, such as

(1) an overall reduction in risk to human health or the environment;
(2) a reduction in the generation of waste materials through recycling, source reduction or other means;
(3) a reduction in the use of hazardous starting materials, reagents, or feedstocks;
(4) a reduction in potential toxicity, human exposure and/or environmental release; or
(5) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

Information provided in this section will be taken into consideration during the review of this substance. See PMN Instructions Manual and Pollution Prevention Guidance manual for guidance and examples.

The flame retardant described in this PMN provides an alternative to toxic brominated aromatic, antimony-based, and red phosphorous materials for use in the electrical and electronics industry. DP-111 provides excellent mechanical properties while enhancing fire retardancy, especially in polyamides and polyesters. Based on like structures, DP-111 is expected to exhibit low toxicity and produces no discernible toxic byproducts during processing and use. In addition, the production methodology for DP-111 produces very few byproducts and makes use of direct recycle of solvents and wash liquors.

Enter Attachment filename for Pollution Prevention Page 11.		☐

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form, test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of any paper attachments. In the Number of Pages column below, enter the inclusive page numbers of each attachment for paper submissions or enter the total number of pages for each attachment for electronic submissions. Electronic attachments can be identified by filename.
Mark (X) the "Confidential" box next to any attachment name or filename you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

#	Attachment Name	Attachment Filename	Number of Pages	Associated PMN Section Number	CBI
001	Structure_DP-111_SANITIZED	Structure for PMN_SANITIZED.pdf	1	Pt.I, Sec.B, 1e.	
002	Manufacturing process flow diagram SANITIZED	PFD_PMN_DP-111_SANITIZED.pdf	1	Pt.2, Sec.A, 1d.	
003	Use Process Flow Diagram DP-111 SANITIZED	USE_PFD_PMN_DP-111_SANITIZED.pdf	1	Pt.2, Sec.B, 1a.	
004	IES Report DP-111 SANITIZED	IES_Report_DP-111 SANITIZED.jpg	1	Pt.I, Sec.B, 1c.	
005	DP-111 Infrared spectrum SANITIZED	DP-111 FTIR SANITIZED.jpg	1		
006	DP-111 Thermogravimetric analysis spectrum SANITIZED	DP-111 TGA SANITIZED.jpg	1		
007	DP-111 MSDS	DP-111 MSDS 7-30-12r7.pdf	5		
008	Particle size distribution	Particle_size.pdf	1	Worksheet: Particle size distribution	

Mark (X) this box if the data continues on the next page. ☐

PMN Page 13

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

The information on this page refers to chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. Give the attachment number (found on page 12) in column (b). The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in __). You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify the review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)		Unit	Mark X if Provided	Attachment Number (b)	Value (c)			Measured or Estimate (M or E)	CBI Mark (X) (d)
					(solid)	(liquid)	(gas)		
Physical state of neat substance			☐		☒	☐	☐	Measured	
Vapor Pressure @ Temperature		°C	☐				Torr		
Density/relative density			☐		0.673		g/cm3	Measured	
Solubility			☐		1.6		g/L	Measured	
@ Temperature	25	°C							
Solvent	DMSO								
Solubility in Water @ Temperature	25	°C	☐		<2		g/L	Measured	
Melting Temperature			☐		320 (dec)		°C	Measured	
Boiling / Sublimation temperature @		Torr	☐				°C		
Spectra			☐	XXX	XXX				X
Dissociation constant			☐						
Octanol / water partition coefficient			☐						
Henry's Law constant			☐						
Volatilization from water			☐						
Volatilization from soil			☐						
pH@ concentration	10%		☐		3.5			Measured	
Flammability			☐						
Explodability			☐		MIE - 1.2 mJ			Measured	
Adsorption / Coefficient			☐						
Particle Size Distribution			☒	008	ave = 10-15 microns			Measured	
Other – Specify			☐						

ATTACHMENT HEADER SHEET

Attachment Number 001

Attachment Name

Structure_DP-111_SANITIZED

Associated PMN Section Number

Pt.I, Sec.B, 1e.

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 002

Attachment Name

Manufacturing process flow diagram SANITIZED

Associated PMN Section Number

Pt.2, Sec.A, 1d.

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 003

Attachment Name

Use Process Flow Diagram DP-111 SANITIZED

Associated PMN Section Number

Pt.2, Sec.B, 1a.

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 004

Attachment Name

IES Report DP-111 SANITIZED

Associated PMN Section Number

Pt.I, Sec.B, 1c.

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 005

Attachment Name

DP-111 Infrared spectrum SANITIZED

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 006

Attachment Name

DP-111 Thermogravimetric analysis spectrum SANITIZED

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 007

Attachment Name

DP-111 MSDS

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

ALPH130711979972581

ATTACHMENT HEADER SHEET

Attachment Number 008

Attachment Name

Particle size distribution

Associated PMN Section Number

Worksheet: Particle size distribution

Does not contain CBI

Report Number

ALPH130711979972581

File: Std Rev FINAL P-13-0690 10-30-2014 RAD Dispo. 05/28/2014
PM: Jesse Miller, 564-2976 TI: M. Johnson, 564-8924

Limited Standard Review Risk Assessment of P-13-0690

SUMMARY

MOEs are calculated using the Rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d (females) with a close analog, [redacted] based on hematological changes (seen in females only). Adjustments for differences in route absorption are not necessary in this case because both inhalation and ingestion routes have an absorption rate of 2%. Occupational inhalation risk is not supported when exposure values are compared to the oral NOAEL. Dermal risk is not calculated because absorption through the skin is expected to be 0%. Risks to the General Population and to the environment are not supported based on no water releases. No testing or PPE are recommended based on the prediction of no risk to any population or to the environment.

I. BACKGROUND

I.A. Regulatory History

Submitter: JJI Technologies, LLC
RAD Dispo: 09/25/2013
Day 90: 06/06/2014

I.B. Chemical Identity

(Per Chemistry Report 12/19/2013, attached)
Chem. Name: [redacted]
CAS RN: [redacted]
Trade Name: DP-111
MW: [redacted]
PV: [redacted] kg/year max [redacted]
Use: Flame retardant for plastics, mainly polyamides and polyesters used in electrical and electronic parts.
P2 Claim: The substance is a substitute for brominated, antimony-based and red phosphorous-based flame retardants.
Mfg /Import: Mfg
PBT Calls P3 B1 T2
Physical States
- Neat: Solid (crystalline)
- Mfg: Solid
- Processing: Solid: [redacted] PMN substance blended into plastic
- End Use: Solid: PMN substance entrained in plastic

Chemical Categories
- Health: Respirable Poorly Soluble Particulates
- Ecotox SAR & Category: Aluminum salts; Aluminum compounds

[redacted]

I.C. Outcome of Analogous Case

[redacted] (structure above right) was submitted by [redacted] for use as a [redacted]. It was Banned Pending Up-Front under the Risk based authority for ecotoxicity concerns in accordance with TSCA section 5(e) Chemical Category (Aluminum Compounds).

Physical / Chemical Properties Affecting Releases and Exposures

(Fate Summary from Focus Report 07/29/2013, attached)
Solid with MP = decomposes >320 C (M)
S 6.4 g/L (M)[1]
VP < 1.0E-6 torr at 25 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 90-99 via sorption, 99.9 via incineration
Time for complete ultimate aerobic biodeg > mo
Sorption to soils/sediments = strong
PBT Potential: P3B1
Migration to ground water = negl

NOTE: Average particle size information indicates 50% is 10 microns (µm) or less and is respirable. As a result the estimated occupational inhalation doses will be reduced by 50%. (Per Focus Report, attached).

Manufacturing and Processing Information:

(Per Chemistry Report 08/26/2013, Process Description section attached)

[redacted]

[1] **NOTE** that this measured value is high for this type of chemical however the submitter stands by this value and the WS test has been reviewed by the Chemist, Justin Roberts, who believes that the test is valid.

I.D. Test Data Submitted (Up-front testing)
(Per Focus Report, attached)
No test data were submitted with this PMN however the studies listed below were submitted with a similar case, P[redacted] (structure on page 3):

- Negative in Salmonella and E coli with and without activation;
- Negative for chromosome aberrations with and without activation;
- Acute oral study in rats, 2 groups of 3 females each, dosed with 2000 mg/kg-bw, no deaths but hunched posture, piloerection and brown staining in the litter tray were noted up to Day 2 in the 2nd group, with complete recovery by Day 3;
- No skin sensitization in Guinea pigs using the Magnusson-Kligman assay at 50% concentration; and
- **Rat 28-day oral (diet) (OPPTS 870.3050, OECD 407) NOAELS = 300 ppm (35.2 mg/kg-bw/d) in females based on blood changes.**

NOTE: The measured water solubility of [redacted], the analog with data, is 24 g/L.

I.E. Focus Decision
(Per Focus Report attached)
P-13-0690 will be placed into a limited standard review for human health risks. As with [redacted], this PMN will be regulated under the TSCA 5(e) category (Aluminum Compounds) Ban Pending-Up Front Testing under the risk-based authority for ecotoxicity concerns. The substance will also be regulated under the exposure-based authority for human health and ecotox concerns.

II. TOXICITY / HAZARD SUMMARIES

II.A. Human Health Summary

II.A.1. Absorption/Metabolism
(Per Leonard Keifer memo, attached)
Based on ATSDR Toxicological Profile for Aluminum, 2008, the absorption rates are Dermal: Insufficient data [assume 0%]; GI tract: 2% (worst case) based on water soluble aluminum compounds; and Lung: 2% based on airborne soluble aluminum compounds.

II.A.2. Human Health Effects of Concern
(Per Focus Report attached)
SAT expressed concerns for blood toxicity based on the 28-day dietary study in rats. SAT also expressed concerns for hypersensitivity, developmental / neurotoxicity, lung effects (uncertain), immunotoxicity, and sensitization. Per USEPA, OAR (attached) there are also particulate concerns for the 50% of the PMN that is respirable, including heart attacks, asthma, reduced lung function, and respiratory symptoms (coughing and difficulty breathing)[2].

Based on the presence of Aluminum (and assuming the Aluminum is bioavailable) there are concerns for: (1) lung effects (asthma-like symptoms, known as potroom asthma and

[2] U.S. EPA Office of Air and Radiation, Health Effects of Particulate Matter
http://www.epa.gov/airquality/particulatematter/health.html

impaired lung function); (2) neurological effects (loss of coordination and memory); and (3) dermatitis[3].

Particle size information indicates that about 50% is 10 microns or less and is respirable. Low / moderate concern was identified at SAT.

II.B. Human Health Toxicity

***Rat 28-day Oral (Diet) Toxicity Test* (OPPTS 870.3050, OECD 407) Using** [redacted]
(Per Review of 28-Day Oral Toxicity Study, V. Morozov, RAD, 05/21/2014 attached)
In a 28-day oral (diet) toxicity study [redacted] 95.7% pure) was administered to Wistar rats (5 animal/sex/group) in the diet for 4 weeks at doses of 0, 100, 300 and 1000 ppm, equal to compound intake of 0; 9.9; 27.8 and 86.9 mg/kg body weight/day for males and 0; 11.4; 35.2 and 121.2 mg/kg body weight/day for females. A satellite group of animals from the control and high dose group were allowed to continue on study post exposure for two weeks (recovery group). There were no compound related effects on mortality or clinical signs. However, males in high dose group (86.9 mg/kg/day) showed statistically significant decrease of body weight gain during recovery period that was related to a decrease in food consumption. Hematological and clinical chemistry changes showed increase in Platelet Count, Mean Corpuscular Hemoglobin Concentration, and decrease in Hematocrit in females at dose 121.2 mg/kg/day. Authors of this study determined the NOAEL value for females at 300 ppm equal to 35.2 mg/kg body weight/day based on blood effects.

II.C. Environmental (Aquatic) Hazard Summary
There will be no water releases as a result there will be no environmental exposure or risk. However because a Chronic COC is needed for a water-trigger, the Ambient Water Quality Criteria for Aluminum[4] (attached) will be used to provide the Chronic COC.

Chronic COC is equivalent to the Criterion Continuous Concentration (CCC) which is an estimate of the highest concentration of a material in surface water to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect. The Acute COC is equivalent to the Criteria Maximum Concentration (CMC) is an estimate of the highest concentration of a material in surface water to which an aquatic community can be exposed briefly without resulting in an unacceptable effect. The CCC and CMC are just two of the six parts of an aquatic life criterion; the other four parts are the acute averaging period, chronic averaging period, acute frequency of allowed exceedence, and chronic frequency of allowed exceedence. Because 304(a) aquatic life criteria are national guidance, they are intended to be protective of the vast majority of the aquatic communities in the United States (Per Kendra Moran, RAD, PC, 05/19-2014).

The CCC for Aluminum at pH 6.5 to 9.0 is 87 µg/L or ppb.

[3] Human Health Risk Assessment for Aluminium, Aluminium Oxide, and Aluminium Hydroxide. Krewski D, et al., Journal of Toxicology and Environmental Health, Part B, Vol. 10, Iss. sup1, 2007
[4] U.S. EPA National Recommended Water Quality Criteria for Aluminum
http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm

III. EXPOSURES AND SURFACE WATER RELEASES

III.A. Occupational Exposures

(Per Engineering Report 8/12/2013 attached)

Manufacturing at [redacted]
Dermal*: 3.1E+3 mg/day (100% Solid)
Inhalation (Particulate): 19 mg/day [redacted]

Use at [redacted]
Dermal*: 3.1E+3 mg/day (100% Solid)
There are 2 different exposure scenarios for inhalation

- Inhalation (Vapor): 19 mg/day [redacted]

*NOTE: Dermal absorption is expected to be 0%, as a result Dermal MOEs are not calculated.

III.B. General Population Exposures

(Per Exposure Report 02/26/2014, pg. 1 attached)
The General Population will not be exposed via Drinking Water or Fish Ingestion because there will be no water releases.

III.C. Surface Water Releases

The submitter has agreed to no water releases, per Jesse Miller, the Program Manager.

IV. RISK ASSESSMENT

IV.A. Human Health Risk Discussion

IV.A.1. Effects Level Used to Determine Risk

Analog Data
The effect level used to determine occupational and general population risk is the rat 28-day oral (dietary) study that was submitted with [redacted]. The study supported a NOAEL of 300 ppm (**35.2 mg/kg-bw/d**) in females based on blood changes. This value will be used to calculate Human Health Margins of Exposure (MOEs).

IV.A.2. Occupational Risk Discussion

Analog Data
When the occupational exposure levels are compared to the rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d (females) with [redacted] based on hematological changes in females (see Table 1) the calculated MOEs of 19 indicate that workers will be at risk for hematological effects from inhalation of the PMN substance during Manufacturing and Use for hematological changes.

A New Chemical Exposure Limit (NCEL) of 2.8 mg/m^3 is calculated (see Table 2) using the female rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d with [redacted] based on hematological changes.

***Table 1. Occupational Exposure MOEs Using the Rat Oral NOAEL* of 35.2 mg/kg-bw/day (in Females) with [redacted]**

Table 1. Occupational Exposure MOE Calculations for P-13-0690 Using the Rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d (females) with [redacted] Effects include hematological changes in females only.

Exposure Scenarios and Values*	Per Day Dose# (mg/day)		Exposure Route Absorption Factor^		Avg BW** All Adults 80 (kg)		PMN Dose (mg/kg-bw/day)		NOAEL Dose (mg/kg-bw/day)		NOAEL Route Absorption Factor^		Margin of Exposure (NOAEL/ PMN Dose)	"Fold" Factor^^ (100/MOE)
Manufacturing: [redacted]														
Dermal-2-Hand Dermal Contact with Solids NOTE: Dermal absorption is expected to be 0%, as a result Dermal MOEs are not calculated														
Inhal.-Particulate	19	x	2%	÷	80	=	0.00	÷ into->	35.2	x	2%	=	148	1
Use as Flame Retardant in Extruded Plastics: [redacted]														
Dermal-High End NOTE: Dermal absorption is expected to be 0%, as a result Dermal MOEs are not calculated														
Inhal.-Vapor	19	x	2%	÷	80	=	0.005	÷ into->	35.2	x	2%	=	148	1

*Inhalation and Dermal doses are from the Engineering Report dated 7/25/2013 and are generated using ChemSTEER. Assumption is an 8 hr day.

^Absorption rates for the specific exposure route expressed as a percentage. Absorption rates are GI 2%, Lung 2%, Skin 0% (Per L.Keifer)

**USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies,Table 8-1, Recommended Values for Body Weight http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf

^^Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the CEB Industrial Hygenist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE

For a NOAEL-based assessment the acceptable MOE is ≥ 100

***Table 2. NCEL Calculation Using the Rat Oral NOAEL of 35.2 mg/kg-bw/day* (in Females) with P-09-0553**

Source: US EPA, OPPT, Response to External Comments on New Chemical Exposure Limits in Toxic Substances Control Act Sec 5 (e) Orders, http://www.epa.gov/oppt/newchems/pubs/ncelresp.pdf

Calculation of a New Chemical Exposure Limit (NCEL) for Non-Cancer Effects														
NOAEL		Uncertainty Factor*		Permissible Daily Dose		Avg Adult BW 80 (♂ & ♀)		Permissible Amt per Person per Day		Internal Amount per Person per Day		Air vol. inhaled in 8 hr work shift		NCEL
mg/kg-bw/d		unitless		mg/kg-d		kg		mg/day		mg/day		m3		**mg/m3**
35.2	÷ by	100	=	0.352	x	80	=	28.16	=	28.16	÷ by	10	=	**2.816**
		(Indiv. Variability of 10)(Inter Sp. Extrapolation of 10)=100												

Steps in Calculating a NCEL using an Inhalation NOAEL

1. The experimental Inhalation NOAEL in mg/kg-bw/day (converted from a NOEC) is divided by an uncertainty factor to give the Permissable Daily Dose in mg/kg-bw/day.
2. The Permissable Daily Dose is multiplied by BW to give the Permissible Amount per Person per Day in mg/day. This is the same as the Internal Amount per Person per Day since the absorption rates are the same for the NOAEL and NCEK (i.e., inhalation).
3. The Internal Amount per Person per Day is divided by 10 m3 which is the air volume inhaled in 8 hr work shift which gives the NCEL in units of mg/m3 per day.

IV.A.3. General Population Risk Discussion

The General Population will not be at risk via Drinking Water or Fish Ingestion because there will be no water releases.

IV.B. Environmental Risk Discussion

Risk to aquatic organisms is not supported based on no water releases.

V. CONCLUSIONS

V.A. Human Health Conclusions

V.A.1. Occupational Health Conclusion

When the occupational exposure values are compared in Table 1 to the rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d acceptable Margins of Exposure (MOEs = 148) are calculated indicating that workers will not be at risk of hematological changes from exposure to the PMN substance during Manufacturing and Use.

Dermal absorption is expected to be 0%, as a result dermal risk is not expected.

V.A.2. General Population Conclusion

General Population risk is not supported.

V.B. Environmental / Aquatic Conclusion
Risk to the aquatic environment is not supported.

VI. RECOMMENDATIONS

No testing or PPE are recommended based on the prediction of no risk to any population or to the environment.

LIST of ATTACHMENTS

Briefing Paper

Case Number: **P-13-0690**

Part I: Background Data

Program Manager: Jesse Miller
Review Team:
CCD Options Date: 07/10/2014
DD Meeting Date:
Day 90: 11/13/2014

Technical Integrator: Maggie Johnson
CCD Dispo Date:
Day In Process: 90

A. CBI Claims:
B. Submitter: JJI Technologies, LLC
C. Chemical Identity: [redacted]
D. Chemical Class:
Health: Respirable Poorly Soluble Particulates
Ecotox: aluminum salts ; [redacted]

E. Structure:

[redacted]

F. Physical/Chemical properties:
VP: Measured Torr @ 25 C
Est. < 0.000001 Torr @ 25 C
s-H2O: Measured g/L
MW: [redacted]
Phys State: Neat: Solid
Manufacturing: Solid
Process/Form: Solid: [redacted] PMN substance blended into plastic
End Use: Solid: PMN substance entrained in plastic

G. Volume: [redacted] kg/yr

H. Use: Flame retardant for plastics, mainly polyamides and polyesters used in electrical and electronic parts. No references found. [redacted] P2REC: CRSS: forward. P2 Claim: The substance is a substitute for brominated, antimony-based and red phosphorous-based flame retardants.

I. Test Data Submitted: TOXICITY DATA for [redacted]:
negative in Salmonella and E coli with and without activation
negative for chromosome aberrations with and without activation
acute oral study in rats - no deaths at 2000 mg/kg
no skin sensitization in guinea pigs using the Magnusson-Kligman assay at 50% concentration
rat 28-day oral (diet) NOAEL = 300 ppm (35.2 mg/kg/d) in females and > 1000 ppm (86.9 mg/kg/d) in males, possible blood effects in females at 1000 ppm (121.2 mg/kg/d)

J. MSDS:
MSDS: Yes
Label: No
General equipment: Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels. Wear appropriate protective eyeglasses or chemical safety goggles as

described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Wear appropriate gloves to prevent skin exposure.

Respirator: A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant a respirator's use.

Health Effects: May be harmful if inhaled. May cause eye and skin irritation. May cause respiratory and digestive tract irritation.

K. SAT Ratings:

Human Health: 1-2 ; Environment: 2 ;

L. Focus Results: P-13-0690 will be placed into a limited standard review with a T.I. and full team for human health risks. This PMN will also be regulated under the TSCA 5(e) category (aluminum compounds) Ban Pending-Up Front Testing under the risk-based authority for ecotoxicity concerns. The substance will also be regulated under the exposure-based authority for human health and ecotox concerns. Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were based on submitted test data for an analog substance [redacted]) and SAR analysis for respiratory poorly soluble particulates. The standard review will look at the analog test data to base the risk assessment. Ecotoxicity hazard concerns were moderate based on SAR predictions for aluminum salts. Chronic risks to the environment were high due to releases to water where the chronic COC of 82 ppb was exceeded 104/[redacted] days (SWC: 1,109.06 ppb) during manufacturing operations and 17/[redacted] days (SWC: 2,396.23 ppb), 22/[redacted] days (SWC: 981.13 ppb), and 41/200 days (SWC: 216.98 ppb) during use operations. Acute risks to the environment were high due to releases to water where the SWCs of 1109.06 ppb during manufacturing operations and 2,396.23 ppb during use operations exceeded the acute COC of 1,050 ppb. The required ecotoxicity testing will be the chronic base set: Fish early-life stage toxicity test (OPPTS 850.1400), Daphnid chronic toxicity test (OPPTS 850.1300), and Algal toxicity test (OCSPP 850.4500). The Fish-early life state toxicity test and Daphnid chronic toxicity test will use flow-though methods while the Algal toxicity test will use static methods. Difficult to test guidelines (OECD 23) must be followed.

This case met [redacted]. No CEB exposure-based criteria were met. The following EAB exposure-based criteria were met: Inhalation Dose (5.02E-03 mg/kg/day), Surface Water Release After Treatment (2.29E+03 kg/yr), Total Release After Treatment (2.29E+04 kg/yr). No fate testing was recommended.

The PMN submission provided information for consideration of P2 recognition, however, the Focus group did not support forwarding the chemical for consideration based on the regulatory outcome.

COC: Chronic – 82 ppb, Acute – 1,050 ppb

Summary of Exposures and Releases

Manu
[redacted]
Inhalation (Particulate): 1.5E+2 mg/day
Dermal; (100% Solid)

Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Air or Incineration or Landfill
Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Incineration or Landfill

Fate Releases to Water (Removal Rate 90%):
SWC: 1109.06 ppb
DW: LADD: 4.82E-04 mg/kg/day; ADR: 5.35E-02 mg/kg/day
>COC (82 ppb) 104/[redacted] days/year

Fate Releases to Air
Stack Air: LADD: 3.10E-03 m/kg/day, ADR: 7.35E-02 mg/kg/day
Fugitive Air: LADD: 5.02E-03 m/kg/day, ADR: 3.00E-01 mg/kg/day

Use
[redacted]
Inhalation (Particulate): 1.5E+2 mg/day
Inhalation (Particulate): 1.5E+2 mg/day
Dermal: 3.1E+3 mg/day (100% Solid)

Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Air or Incineration or Landfill
Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Air or Incineration or Landfill
Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Incineration or Landfill
Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Incineration or Landfill
Releases to Water: [redacted] kg/site-day over [redacted] days/yr
Or Incineration or Landfill

Fate Releases to Water (Removal Rate 90%):
SWC: 2396.23 ppb
DW: LADD: 2.20E-04 mg/kg/day; ADR: 0.11 mg/kg/day
>COC (82 ppb) 17[redacted] days/year

PDM2
Fate Releases to Water (Removal Rate 90%):
SWC: 981.13 ppb
DW: LADD: 8.40E-05 mg/kg/day; ADR: 4.48E-02 mg/kg/day
>COC (82 ppb) 22[redacted] days/year

PDM3
Fate Releases to Water (Removal Rate 90%):
SWC: 216.98 ppb
DW: LADD: 8.85E-05 mg/kg/day; ADR: 9.91E-03 mg/kg/day
>COC (82 ppb) 41[redacted] days/year

Fate Releases to Air
Stack Air: LADD: 3.11E-04 m/kg/day
Fugitive Air: LADD: 5.03E-04 m/kg/day, ADR: 1.90E-01 mg/kg/day

Part II: New Information

From 6/10/briefing:

Much debate centered around the solubility of the PMN substance. The estimated soubility in the initial review chem report was < 0.1 g/L. However, it was thought that the the material would be insoluble and the company was asked to perform a solubility study. The submitter determined that the solubility of the PMN substance was 6.4 g/L. Nobody believed this number, but after reviewing the data, the chemist deemed the study to be acceptable.

The company addressed all their water releases.

RAD's Conclusion

MOEs are calculated using the Rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d (females) with a close analog, [redacted] based on hematological changes (seen in females only). Occupational inhalation risk is also calculated using the NIOSH REL of 5 mg/m^3 (respirable portion) for exposure to Aluminum dust. Occupational inhalation risk is supported when exposure values are compared to **both** effects levels. A New Chemical Exposure Limit (NCEL) of 2.8 mg/m^3 is calculated using the female rat 28-day oral (diet) NOAEL of 35.2 mg/kg-bw/d. Dermal risk is not calculated because absorption through the skin is expected to be 0%. Risks to the General Population and to the environment are not supported based on no water releases.

RAD's RECOMMENDATIONS:

Human Health Recommendations
Workers should wear personal protective equipment, specifically a particulate respirator that is adequate to bring the MOEs up to the protective level of ≥100. Note that the Fold Factor for inhalation exposure as compared to the rat 28-day oral (diet) NOAEL is 3 (Table 1) and the Fold Factor for inhalation exposure as compared to the NIOSH REL is 23 (Table 3).

Testing Recommendations
Based on supported occupational inhalation risk and occupational inhalation exposures of longer duration (Mfg = [redacted] and Use = [redacted] days with exposure [redacted] per day) the recommended testing is the 90-Day Inhalation Toxicity Test with the PMN substance according to guidelines OPPTS 870.3465 or OECD 413.

Newer Information:
RAD decided that the NIOSH REL for aluminum dust was not appropriate for this case since the PMN substance is not [redacted] and is soluble in water. RAD also recalculated the fold factor for inhalation exposure to be 5 using the rat 28-day oral NOAEL.

New Newer Information
The worker inhalation exposure in RAD's Risk assessment was changed from 150 mg/day to 19 mg/day in order to be consistent with the Standard review engineering report. There is no longer an inhalation risk to workers. Also, the chronic CoC was changed form 82 ppb to 87 ppb based upon the Ambient Water Quality Criteria for Aluminum.

[redacted]

The PM recommends that this case be dropped with a Non-5(e) SNUR with:

1. Water trigger of 87 ppb
2. worker protection respirator with an APF of 10
3. recommended testing: 90 day inhalation Toxicity Test OPPTS 870.3465 or OECD 413 and the chronic base set.

Part IV: Risk Summary

A. Health Effects:
Absorption is nil all routes based on physical/chemical properties. However, [redacted], [redacted] caused effects in a 28-day oral study in rats and was given an absorption call of nil through the skin but absorbed through the lungs and GI tract. The water solubility for [redacted] is stated to be much higher than the water soubility for this material (24 g/L vs < 0.1 g/L). If absorption is nil through the lungs, then there is concern for lung efects if respirable particles are inhaled base don information for poorly soluble respirable particulates. If the PMN material is analogous to [redacted], there is concern for blood toxicity based on the 28-day dietary study in rats and concern for hypersensitivity, developmental neurotoxiicty, and immunotoxicity if Al is bioavailable. Particle size information indicates that about 50% is 10 microns or less. Low moderate concern.

B. Environmental Effects:

Ecotox: predicted (P) and measured (M) toxicity value is mg/L (ppm) are:

Fish 96-h LC50:	90(P)
Daphnid 48-h LC50:	47(P)
Green algal 96-h EC50:	4.2(P)
Fish Chronic Value:	27(P)
Daphnid ChV:	7.9(P)
Algal ChV:	0.82(P)

C. Environmental Releases and Exposures:

D. Risk Estimates:

Part V: Exposure Criteria Met

Exposure Based Review (Chemistry):	● Yes ○ No	**Exposure Based Review (Health):**	● Yes ○ No
Exposure Based Review (Ecotox):	● Yes ○ No	**Exposure Based Review (Occupational):**	● Yes ○ No
Exposure Based Review (Non-Occupational):	○ Yes ● No	**Exposure Based Review (Environmental):**	● Yes ○ No

[redacted]

Part VI: Tests

Final Testing Recommendation
Health:
Eco:
Fate:
Other:

Comments:

Part VII: Other Factors

A. Substitutes:

B. Benefits:

C. Other Uses: None found.

D. Other:

Part VIII: Regulatory History

[redacted]-Consent order

Comments:

Last Updated by

Document Created by Jesse Miller **on** 06/10/2014

SAT Report

PMN Number: **P-13-0690**
SAT Date: **7/19/2013**
Print Date: **4/22/2015**

Related cases: [redacted]
Health related cases: [redacted]
Ecotox related cases: Similar Case [redacted]

Concern levels:

Type of Concern:	Health	Eco	Comments
Level of Concern:	1-2	2	

Persistence	Bioaccum	Toxicity	Comments
3	1	2	

Exposure Based Review:
Health: Yes
Ecotox: Yes

Routes of exposure:
Health: Inhalation
Ecotox: All releases to water
Fate: ;

P2Rec Comments:
Comment: Forward

Keywords:
Keywords: UNCERT-LUNG/BLOOD/SENS/DEVEL-NEURO/IMMUNO, AQUATOX-A,

Summary of Assessment:

Fate:
Fate Summary: P-13-0690
FATE:
Solid with MP = Dec. >320 C (M)
S < 100 mg/L at 25 C (M)
VP < 1.0E-6 torr at 25 C (E)
H < 1.00E-8 (E)

POTW removal (%) = 90-99 via sorption
Time for complete ultimate aerobic biodeg > mo
Sorption to soils/sediments = strong
PBT Potential: P3B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Absorption is nil all routes based on physical/chemical properties. However, [redacted] caused effects in a 28-day oral study in rats and was given an absorption call of nil through the skin but absorbed through the lungs and GI tract. The water solubility for [redacted] is stated to be much higher than the water soubility for this material ([redacted] vs < 0.1 g/L). If absorption is nil through the lungs, then there is concern for lung efects if respirable particles are inhaled base don information for poorly soluble respirable particulates. If the PMN material is analogous to [redacted], there is concern for blood toxicity based on the 28-day dietary study in rats and concern for hypersensitivity, developmental neurotoxiicty, and immunotoxicity if Al is bioavailable. Particle size information indicates that about 50% is 10 microns or less. Low moderate concern.

Test Data: TOXICITY DATA for [redacted]:
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Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	90		
daphnid	**48-h**	**LC50**	47		
green algal	**96-h**	**EC50**	4.2		
fish	**_**	**chronic value**	27		
daphnid	**_**	**chronic value**	7.9		
algal	**_**	**chronic value**	0.82		
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for inorganic aluminum compounds; SAR chemical class = aluminum salt-[redacted] solid with mp = 310 C (M); pH7; effective concentrations based on 100% active ingredients and mean measured

concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	82	
SARs	aluminum salts	
SAR Class	[redacted]	
Ecotox Category	Aluminum Compounds	

Ecotox Factors Comments:

SAT Chair: Becky Jones